



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: January 6, 2023

SUBJECT: Efficacy Review for JESSE,
EPA Reg. No. 6297-2
Action Code Case: 00389541
E-submission No. 79546

FROM: Nicole Karikari
Efficacy Branch
Antimicrobials Division (7510M)
Date Signed: January 6, 2023

Nicole Karikari

THRU: Sophie Nguyen
Efficacy Branch
Antimicrobials Division (7510M)
Date Signed: January 5, 2023

Sophie Nguyen

TO: Tara Silva Flint, Acting PM 31/Karen Leavy-Munk
Regulatory Management Branch I
Antimicrobials Division (7510M)

APPLICANT: Bissell Homecare, Inc.

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides.....	0.21%
Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides.....	0.21%
<u>Other Ingredients</u>	99.58%
<u>Total</u>	100.00%

I. BACKGROUND

Product Description (as packaged, as applied): Concentrated Liquid (Dilutable)

Submission type: Label Amendment

Currently registered efficacy claim(s): Dilutable liquid non-food contact sanitizer (bactericidal) product for hard, non-porous surfaces.

Requested action(s): The applicant is submitting data to support a label amendment to add non-food contact sanitizer claims against *Salmonella enterica* (ATCC 10708). In addition, the applicant proposed the following change to the use dilution instructions:

“In the initial application, the machine User Manuals were provided to the Agency but not incorporated into the stamped, accepted label because the use dilution instructions were present on the labeling for the product container. A subsequent amendment removed those use dilution instructions from the container label, placing them in the manuals only, which required the User Manuals to become part of the EPA stamped label. This action proposes to blend the two options. In some instances where the bottle is fully labeled with use dilution instructions, the User Guide will accompany a floor machine but is not a necessary piece of the label. In other instances, if the label refers to the use dilution ratio but not how to dilute, the User Manual is a required piece of the label. Depending on the different floor machine models, one or another scenario may be present. The proposed master label incorporates this flexibility. One copy of the enclosed label has all changes tracked. Other modifications are included to accommodate various floor machine models, and the marketing claims are alphabetized and reorganized for clarity.”

Documents considered in this review:

- Cover letter from applicant to EPA dated August 29, 2022
- Proposed label dated August 24, 2022
- Data Matrix (EPA Form 8570-35) dated August 29, 2022
- One efficacy study
 - MRID 51977301
- Confidential Statement of Formula (EPA Form 8670-4)
 - Basic Formulation dated May 17, 2018

II. PROPOSED DIRECTIONS FOR USE

“[Section I. Directions and Text for Use on Floors with a BISSELL Machine]

[For use with (BISSELL) (CrossWave) (with steam) (and) (SpinWave) (Sanitaire (SC930 Series) (machines).]

[Suitable for use with (BISSELL) (CrossWave) (with steam) (and) (SpinWave) (Sanitaire (SC930 Series) (machines)]

[For use with BISSELL Wet Cleaning System machines.]
(Flush machine with clean water after use.)

[Note to Reviewer: The below statement must appear on the label should the product be for use with a BISSELL machine with a fill line or instruction to meet a fill line. **Otherwise, it is optionally included.**]

Read [User] [Guide] [Manual] [Brochure] [directions on machine] fully prior to use.
[Note to Reviewer: When Section I. "Option A" Use Directions appear on the antimicrobial label, the User Manual is not a piece of the required product label. When Section I. "Option B" Use Directions appear on the antimicrobial label, the User Manual is considered part of required labeling.]

[Option A - Note to Reviewer: By filling to the lines indicated on the tank, the solution will mix at an equivalent to 1 part formula + 6 parts water. For large areas, 4 fl oz of product is mixed with 24 fl oz water or equivalent dilution. For small areas 2 fl oz of product is mixed with 12 fl oz of water or equivalent dilution.]

How to use (in) (with) (CrossWave) (machine):

1. Fill machine formula tank with (warm) water to Water fill line (for small areas (to) (-) 12 fl oz., for large areas (to) (-) 24 fl. oz.). Then add formula to Formula fill line (for small areas (to) (-) 2 fl. oz., for large areas (to) (-) 4 fl. oz.). Cap tank and return to machine.
2. Use machine as directed in the User Guide under the heading "Cleaning Your Hard Floors". To clean: Hold the spray trigger to apply solution to floor. To Sanitize: Remove visible soil. Hold spray trigger to apply solution to floor. Allow to remain wet for 5 minutes.
3. Empty (dirty water) (pick-up) tank down the drain.
4. Flush tank, filter, and float with clean water after use. Allow to air dry.
5. Stay off cleaned area until completely dry.

How to use (in) (with) (SpinWave) (machine):

1. Fill machine formula tank with (warm) water to Water fill line (for small areas (to) (-) 12 fl oz., for large areas (to) (-) 24 fl. oz.). Then add formula to Formula fill line (for small areas (to) (-) 2 fl. oz., for large areas (to) (-) 4 fl. oz.). Cap tank and return to machine.
 2. Use machine as directed in the machine User Guide under the heading "Cleaning Your Sealed Hard Floors". To clean: Push the SPRAY button to dispense solution. To Sanitize: Remove visible soil. Push the SPRAY button to dispense solution. Allow to remain wet for 5 minutes.
 3. Stay off cleaned area until completely dry.
- (Note: Any solution remaining in the clean water tank should be emptied prior to machine storage.).

[Option B – [Note to Reviewer: By filling to the lines indicated on the BISSELL machine tank, the solution will mix at a dilution equivalent to 1 part formula + 6 parts water.]

[Option B.1.]

How to use (in) (with) (CrossWave) (with steam) ([Sanitaire] [SC930 [insert other series number here] Series]) (Robot) (insert equivalent brand name) (machine):

1. [for machines with a small and large fill line]

Fill machine formula tank with (warm) water to Water fill line for small areas. Then add formula to Formula fill line for small areas. Or add (warm) water to Water fill line for large areas, and then add formula to Formula fill line for large areas. Water to concentrate ratio is 6:1. Cap tank and return to machine.

[for machines with only one fill line:]

Fill machine formula tank with (warm) water to Water fill line. Then add formula to Formula fill line. Water to concentrate ratio is 6:1. Cap tank and return to machine.

2. Use machine as directed in the [User] [Guide] [Manual] [Brochure] [directions on machine] under the heading “Cleaning Your Hard Floors”.

To clean: [Hold] [Press] the spray trigger ((or) for [Robot] [insert Robot brand name here]) set to “Clean” (mode) to apply solution to floor. (For heavier soils press the steam button, if available.) To Sanitize: Remove visible soil. [Hold] [Press] spray trigger ((or) for [Robot] [insert Robot brand name here]) set to “Spot” Mode) to [apply] [dispense] solution to floor. Allow to remain visibly wet for 5 minutes.

3. Empty (dirty water) (pick-up) tank down the drain.

4. Flush tank, filter and float with clean water after use. Allow to air dry.

5. Stay off cleaned area until completely dry.

How to use (in) (with) (SpinWave) (with steam) (Sanitaire) (Robot) (machine):

1. [for machines with a small and large fill line]

Fill machine formula tank with (warm) water to Water fill line for small areas. Then add formula to Formula fill line for small areas. Or add (warm) water to Water fill line for large areas, and then add formula to Formula fill line for large areas. Water to concentrate ratio is 6:1. Cap tank and return to machine.

[for machines with only one fill line:]

Fill machine formula tank with (warm) water to Water fill line. Then add formula to Formula fill line. Water to concentrate ratio is 6:1. Cap tank and return to machine.

2. Use machine as directed in the machine [User] [Guide] [Manual] [Brochure] [directions on machine] under the heading “Cleaning Your Sealed Hard Floors”.

To clean: [Push] [Hold] the SPRAY button to dispense solution ((or) for [Robot] [insert Robot brand name here]) set to “Clean” (mode). (For heavier soils press the steam button, if available.) To Sanitize: Remove visible soil. [Push] [Hold] the SPRAY button ((or) for [Robot] [insert Robot brand name here]) set to “Spot” Mode) to [apply] [dispense] solution. Allow to remain visibly wet for 5 minutes.

3. Stay off cleaned area until completely dry.

[Note: Any solution remaining in the clean water tank should be emptied prior to machine storage.]

[Option B.2]

How to Use (with pre-measured packets):

[For Use with pre-measured sachets/packets in machine with an integrated dispenser in formula-only tank]

1. Fill the Clean Water Tank with (warm) water to the Fill line indicated on the tank. (Use warm (140F/60C max) water.)

2. Lift Formula lid and place a (BISSELL) [insert product name] [sachet] [packet] [pouch] in holder.

3. Use machine as directed [in the machine [User] [Guide] [Manual] [Brochure]] [on machine] under the heading “Cleaning Your Sealed Hard Floors”.

To clean: Push the SPRAY button to dispense solution. To Sanitize: Remove visible soil. Push the SPRAY button to dispense solution. Allow to remain visibly wet for 5 minutes.

4. Stay off cleaned area until completely dry.

Note: Any solution remaining in the clean water tank should be emptied prior to machine storage.

[For Use with pre-measured sachets/packets in machine withOUT an integrated dispenser in formula-only tank]

1. Fill the Clean Water Tank with (warm) water to the Fill line indicated on the tank. (Use

warm (140F/60C max) water.)

2. Tear open (BISSELL) [insert product name] [sachet] [packet] [pouch] at indicated notch and pour contents into tank.

3. Use machine as directed in the machine User [Guide] [Manual] [Brochure] under the heading "Cleaning Your Sealed Hard Floors". To clean: Push the SPRAY button to dispense solution. To Sanitize: Remove visible soil. Push the SPRAY button to dispense solution. Allow to remain visibly wet for 5 minutes.

4. Stay off cleaned area until completely dry.

Note: Any solution remaining in the clean water tank should be emptied prior to machine storage.

[Section II. Directions and Text for Use on Floors with a NON-BISSELL Machine]

[Use directions for a non-BISSELL/Fill line machine:]

How to use with a hard floor cleaning device:

1. Fill machine formula tank with 4 fl. oz. of product [insert brand name] and 24 fl. oz. (warm) water (or equivalent dilution). [Fill machine formula tank with product and water as indicated in the table (above)(below).]

2. Pre-clean floors to remove visible soil.

3. To Sanitize: Spray or apply solution on hard, non-porous floors and allow to remain visibly wet for 5 minutes.

4. Stay off cleaned area until completely dry.

Note: Any solution remaining in the solution tank should be emptied prior to machine storage.

[Section III. Directions and Text for Use on Floors without a floor cleaning device]

[Directions for Mop & Bucket]

How to mop your floor (without a BISSELL machine) [Directions for Use]:

1. Clean the floors to remove visible soil.

2. Fill bucket [container] with [1 gallon] of (warm) (tap) water and add 22 fl. oz. of product (or equivalent dilution) [Note to Reviewer: may replace dilution values as presented in Product Dilution Instructions Table].

3. Mop hard, non-porous floors until thoroughly wet, rewetting the mop as needed.

4. Allow floors to remain visibly wet for 5 minutes. (Stay off sanitized area until completely dry.)

5. Replace use solution when it becomes heavily soiled.

[Section IV. Directions and Text for Use on Non-Floor Hard, Non-Porous Surfaces]

To sanitize hard, non-porous, non-food contact surfaces:

1. Mix 4 fl. oz. of product [insert product name] with (warm) 24 fl. oz. tap water (or equivalent dilution) [Note to Reviewer: may replace dilution values as presented in Product Dilution Instructions Table].

2. Clean to remove visible soil.

3. Apply product with a cloth or trigger sprayer until thoroughly wet (or immerse items in a bucket [container]. Make fresh solution if it becomes heavily soiled or diluted.).

4. Allow surfaces to remain visibly wet for 5 minutes.

5. Allow to air dry(, or wipe dry after contact time)."

III. STUDY SUMMARIES

1.	MRID	51977301	
Study Title		Standard Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces	
Study Objective		Non-Food Contact Sanitizer	
Testing Lab; Lab Study ID		Analytical Lab Group – Midwest; A32548	
Experimental Start Date		April 1, 2021	Study Completion Date: January 24, 2022
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Salmonella enterica</i> (ATCC 10708)	
Test Method		ASTM E1153-14 – Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces; Protocol Number: BLL01111820.NFS (copy provided)	
Application Method		"Following the completion of drying, each of the five test carriers were transferred to individual sterile 2 oz. (60 ml) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 5.0 ml of prepared test substance was transferred to each jar. The liquid completely covered the carriers during exposure."	
Test Substance Preparation	Name/ID	Jesse, EPA Reg. No. 6297-2	
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	Lot 1, Lot 2	
	Preparation	Tested concentration: LCL Tested Dilution: 1:7 dilution (0.95 parts test substance + 6 parts diluent) Diluent: 400 ppm AOAC Synthetic Hard Water	
Soil load		5% Fetal Bovine Serum (FBS)	
Carrier type, # per lot		Glass 1" x 1" carriers; "Following the completion of drying, each of the five test carriers were transferred to individual sterile 2 oz. (60 ml) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 5.0 ml of prepared test substance was transferred to each jar. The liquid completely covered the carriers during exposure."	
Test conditions		Contact time: 4 minutes 50 seconds Temperature: 20°C Relative humidity: 19%	
Neutralizer		Tryptone-Azolectin-Tween Broth + 0.14% Lecithin + 1.0% Tween 80	
Incubation conditions		48±4 hours at 35-37°C (aerobic)	
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendment: "Per Sponsor's request, the protocol is amended to change the test substance dilution to "0.95 parts test substance + 6 parts AOAC Hard Water." No Protocol Deviations were reported.	

IV. STUDY RESULTS

Non-Food Contact Sanitizer Efficacy

MRID	Organism	Contact Time		Results			Population Control Average Log ₁₀ CFU/carrier
			Lot No.	Average Log ₁₀ CFU/ ml	Geometric Mean	Percent Reduction	
Concentrated liquid; 1:7 dilution, 5% soil load present							
51977301	Salmonella enterica (ATCC 10708)	4 minutes 50 seconds	Lot 1	< 1.63	< 4.27 x 10 ¹	> 99.9964%	6.07
			Lot 2	2.60	3.98 x 10 ²	99.966%	6.07

V. STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
51977301	Non-Food Contact Sanitizer	Hard, non-porous surface	Concentrated liquid; 1:7 dilution (0.95 parts test substance + 6 parts diluent)	4 minutes 50 seconds	5% FBS	400 ppm AOAC Synthetic Hard Water	• <i>Salmonella enterica</i> (ATCC 10708)	Yes

VI. LABEL COMMENTS

Label Date/Identification Number: August 24, 2022 (clean copy)

1. The proposed label claims that the product, JESSE, EPA Reg. No. 6297-2, when diluted at 1:7 dilution (0.95 parts test substance + 6 parts 400 ppm AOAC Synthetic Hard Water), is an effective non-food contact sanitizer against the following on visibly clean hard, non-porous surfaces for a 5-minute contact time:

- *Salmonella enterica* (ATCC 10708)

This claim is **acceptable** as it is supported by the submitted data.

2. Make the following changes to the proposed label:
 - a. Throughout the label and user manual,
 - i. Especially on page 2, specify each instance of “wood” and “wood floor” with “sealed, nonporous”. The descriptions should be bracketed together.
 - ii. Revise each instance of “Allow to remain wet...” to “Allow to remain **visibly** wet...”.
 - iii. Remove reference to sanitizing of messes. For example, revise “sanitize floors after tough messes like pet accidents” to “sanitize floors after tough messes, like pet accidents, have been cleaned up”. “Sanitizes and loosens (tough) stains” should also be removed or revised accordingly. Sanitizing of messes may imply messes can be sanitized. Messes can be cleaned but not sanitized; and any visible soil should be removed prior to sanitizing.
 - iv. Data were not conducted using hot water, which potentially could act to inactivate the antimicrobial effect of the active ingredient at certain temperature. Please refrain from associating the steam or hot water setting with the use of the product to sanitize a surface. This setting may be used to clean and deodorize.
 - v. In the user manual, please specify hard surface/floor as “hard, non-porous surface/floor”.
 - b. On page 4, the items listed under Non-Floor Surfaces should specify hard, non-porous material (e.g., walls, vanities, etc.).
 - c. Starting on page 11, under Sanitizing Claims, when the claims reference both cleaning and sanitization in one step, specify that the use-directions for sanitization should be followed (e.g., preclean visibly soil before sanitization, etc.).
 - d. On page 12,
 - i. Remove “destroys” when describing kill claims as this term implies heightened efficacy. This word may be replaced with “kills”.
 - ii. Remove “Easy (sanitizing)” as this implies enhanced efficacy.